

**REMARKS**

The foregoing amendments and these remarks are in response to the Office Action dated March 18, 2008. Applicant respectfully requests a three month extension of time and authorization is hereby given to charge Deposit Account No. 50-0951 for the appropriate fees.

At the time of the Office Action, claims 1, 3-7, 9-12, 14 and 23 were pending in the application. In the Office Action, claims 1-7, 13 and 15-21 were rejected under 35 U.S.C. §103(a). The rejections are discussed in more detail below.

**I. Rejections to the claims based upon Art**

Claims 1-7, 13 and 15-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,480,402 to Kim (hereafter "Kim") in view of U.S. Patent No. 4,101,985 to Baumann ("Baumann") and U.S. Patent No. 6,692,498 to Niiranen ("Niiranen") and U.S. Patent Publication No. 2004/0181228 to Wagner ("Wagner").

Claim 1 has been amended by adding the feature of a fragment fixation pin embraced by a seat of the intermediate plate element. This feature was already described in previous Claim 4, as well as thoroughly discussed in the specification (for instance in paragraphs 67 to 74 and 80 to 84) and visible in the figures. The original wording of Claim 4 has been revised in order to unambiguously and positively introduce the fragment fixation pin. Claim 4 has been cancelled and the dependencies of claims 5 and 6 have been modified accordingly.

Method Claim 23 has been amended by adding the step of inserting the fragment fixation pin through a hole of the intermediate plate element; such a step is described in paragraph 80 of the original filed description.

A new independent Claim 24 has been added: this claim lists all the features of amended Claim 1 except for the partial thread description introduced in response to the previous office action. Also a new Claim 25 depending from claim 24 is proposed; this claim introduces the feature of a sliding fit between the fragment fixation pin and the hole hosting it, as originally described in paragraph 81 of the description.

Amended Claim 1 as well as new Claim 24 are considered to be new and nonobvious over the prior art cited by the Examiner.

In first instance, Applicants note that four documents are combined in order to attack claim 1, and that this is in Applicants views a strong indicator of the inventiveness of such a claim.

Furthermore, only one of the cited documents (*Kim*) refers to the surgical technique pertaining to the present application, i.e. to the reduction of proximal humeral fractures by means of a humeral nail. *Niiranen* discloses plates meant for cranio-maxillofacial surgery; the *Baumann* teaching relates to a hip-joint; *Wagner* describes the holes provided in plates and not in humeral nails: nevertheless the examiner does not say a single word to justify the adoption of such references. Applicants note that the design of orthopedic devices is a highly specialized field and solutions adopted for one surgical technique are very specific and can never be easily transposed to a different application. There is thus no assumption in this art that a person of ordinary skill in the art would use techniques from any one surgical technique in any other. Applicants believe that the rejection has not therefore made out a *prima facie* case for obviousness of the claims, as no evidence has been given as to why a person of ordinary skill in the art would combined the references.

Nonetheless, and purely in the interests of expeditious prosecution, Applicants amend the Claims herein and to rely on the presence of the fragment fixation pin(s) in order to stress the difference between the presently claimed devices and methods, and the prior art.

Applicants note that none of the cited documents disclose a fixation system comprising the following four structural elements:

1. a humeral nail;
2. at least an intermediate plate;
3. at least a locking screw connecting the humeral nail to the intermediate plate;
4. at least a fragment fixation pin attached to the intermediate plate.

The presence of the fragment fixation pin(s) within the frame of the described system solves the problem of fastening all humeral head fragments to the humeral nail; specifically it allows fixation even of the fragments which do not lie along the direction of the locking screw (see paragraph 20 of the description). Indeed, these fragments are pinned to the intermediate plate which is bridged to the humeral nail through the locking screw.

Thus, Claim 1, and dependent Claims 2, 3, 5-7, 9-12, and 14 are believed to relate to patentable subject matter, and to be in condition for allowance. Similarly, as Claim 24 recites all the features of amended Claim 1 except for the partial thread description introduced in response to the previous office action, this claim is also believed allowable.

Note that new dependent Claim 25 introduces another inventive feature of the system, i.e. the sliding fit of the fragment fixation pin within its hole, which allows free orientation of the pin with respect to the plate (paragraph 81). Claim 25 is also allowable because of its dependence upon an allowable base claim.

Amended method Claim 23, which now cites the surgical step of inserting the fragment fixation pin within the frame of the system, should also be considered new and nonobvious for the same reasons outlined above.

## II. Conclusion

Applicant has made every effort to present claims which distinguish over the prior art, and it is thus believed that all claims are in condition for allowance. Nevertheless, Applicant invites the Examiner to call the undersigned if it is believed that a telephonic interview would expedite the prosecution of the application to an allowance. In view of the foregoing remarks, Applicant respectfully requests reconsideration and prompt allowance of the pending claims.

Respectfully submitted,

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Mark D. Passler  
Registration No. 40,764  
Sarah E. Smith  
Registration No. 50,488  
**AKERMAN SENTERFITT**  
Post Office Box 3188  
West Palm Beach, FL 33402-3188  
Telephone: (561) 653-5000